

Application No.: 10/735,602

Docket No.: JCLA10516-R2

**REMARKS****I. Present Status of the Application**

The Office has rejected claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response thereto, Applicant has amended independent claims 1 and 11 to describe the claimed invention more explicitly. It is believed that no new matter is added by way of the amendments made to the instant application. After entry of the proposed amendments, Applicant respectfully traverses these rejections for at least the following reasons. It is submitted that the presently pending claims 1-14 are placed in proper condition for allowance, and reconsideration of all pending claims is respectfully requested.

**II. Discussion of Claim Rejections under 35 U.S.C. 112, Second Paragraph**

*Claims 1-14 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite.*

In response thereto, Applicant has amended independent claims 1 and 11 to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The supporting ground for the amendments made to claims 1 and 11 can be found at least in the description of the specification without entering any new matter.

The feature regarding "the biological material is delivered without using carriers" recited in previously-presented claim 1 has been replaced with "the biological material is delivered without

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using micro-carriers or particle carriers" for clarification. In addition, the feature regarding "the biological material is delivered without using carriers" recited in previously-presented claim 11 has been replaced with "the nucleic acid is delivered without using micro-carriers or particle carriers".

According to the disclosure of the specification, the instant invention has disclosed "an appropriate design includes an application of sample solution **without micro-carriers** ...the gene gun operation uses the sample solution **without containing particle carriers in the solution**" (p. 8, lines 1 and 8). The instant application has also disclosed in an embodiment that "[T]he **particle-free DNA solution** contains 0.2  $\mu$ g pEGFP-N2 vector" (p. 21, line 24). Since the description of the specification has disclosed that the sample solution contains neither particle carriers nor micro-carriers therein, the biological material contained in the sample solution is delivered without using micro-carriers or particle carriers, which means the amendments made to claims 1 and 11 is fully supported by the disclosure.

A solvent or water (construed as carriers by the Office) refers to a liquid form in a solution. Accordingly, Applicant respectfully submits that a solvent or water contained in the sample solution cannot belong to the scope of the micro-carriers or particle carriers, as set forth in amended claims 1 and 11.

Further, the limitation of "the biological material" in lines 20-21 of claim 11 has been redefined as "the nucleic acid" for providing sufficient antecedent basis for the feature.

In light of the foregoing regards, it is respectfully submitted that claims 1 and 11, as amended, are definite, and the rejections thereof should therefore be rendered moot. Applicant further

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respectfully points out that if independent claims 1 and 11 are patentable over the prior art of record, claims 2-10 and 12-14, based on their dependence upon respective claims 1 and 11, are allowable as a matter of law, because these dependent claims contain all features of their base claims.

Hence, favorable reconsideration of the instant application and withdrawal of these rejections to the pending claims are hereby courteously solicited.

### **III. Regarding Prior Art Made of Record**

*The Office has considered Lin et al. (US 6,436,709) and Held et al. (WO 02/44391) pertinent to applicant's disclosure.*

After carefully considering the remarks set forth in this Office Action and the prior art made of record, Applicant respectfully disagrees on the pertinence of Held et al. (WO 02/44391, referred to hereinafter as "Held") proposed by the Office.

More specifically, Held discloses "DNA carried in aerosol droplets of this small size penetrates cells **only because of the speeds attained by aerosol droplets**" (page 8, lines 13-14). As shown in FIG. 1 disclosed by Held, a temperature controller 17 is proposed to control the temperature in the entrainment housing 11 to a range of about 32°C to 80°C (page 14, lines 6-9), and a vacuum chamber 13 is proposed to provide a partial vacuum for introducing the aerosol droplets into target cells (page 15, lines 1-9). Accordingly, the combination of the pressurized gas in the entrainment and the partial vacuum in the vacuum chamber 13 accelerates the aerosol droplets to a desirable speed based on the foregoing designs.

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Moreover, Held also states that “[S]peeds achieved by the aerosol beam method of the invention are supersonic and can reach 2000 meters/second. By contrast, top speed achieved by the particle gun is 200 meters/second” (page 8, lines 15-16). That is to say, Held’s method for introducing molecules into the target depends upon an ultra high speed that cannot be achieved by the particle gun. Thus, Applicant submits that the method taught by Held is in a different field of endeavor because Held discloses the molecules are accelerated by the specific aerosol beam apparatus to achieve an ultra high speed.

As such, the instant invention discloses in the specification, among other things, “the sample solution (i.e. biological material containing solution) is accelerated by a gas to a velocity of about 200 to 300 meter/sec, and this speed does not exceed the speed of sound” (page 8, lines 13-15). Applicant submits that the sample solution is delivered without containing micro-carriers or particle carriers therein owing to the contour design of the spray nozzle and the disposition of the material delivery system, as claimed in the instant invention, and the instant invention indeed shows the unexpected results when compared with the prior art. Thus, it will basically destroy the principle of Held’s teaching in the art that the aerosol beam delivery is applied to an apparatus which cannot achieve the desired ultra high speed.

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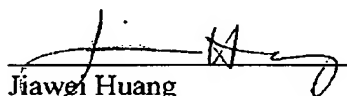
**CONCLUSION**

For at least the foregoing reasons, it is believed that all pending claims are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

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